DHHS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2004D–0493]

Draft Guidance for Industry on Recommended Approaches to Integration of Genetic Toxicology Study Results; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Recommended Approaches to Integration of Genetic Toxicology Study Results." This draft guidance is intended to inform industry on how the Center for Drug Evaluation and Research (CDER) views positive findings in genetic toxicology assays, and to provide recommendations to industry on how to proceed in assuring safety of healthy subjects or patients when results in genotoxicity studies suggest a potential cancer or genetic hazard.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630

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Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5346.

SUPPLEMENTARY INFORMATION:

I. Background

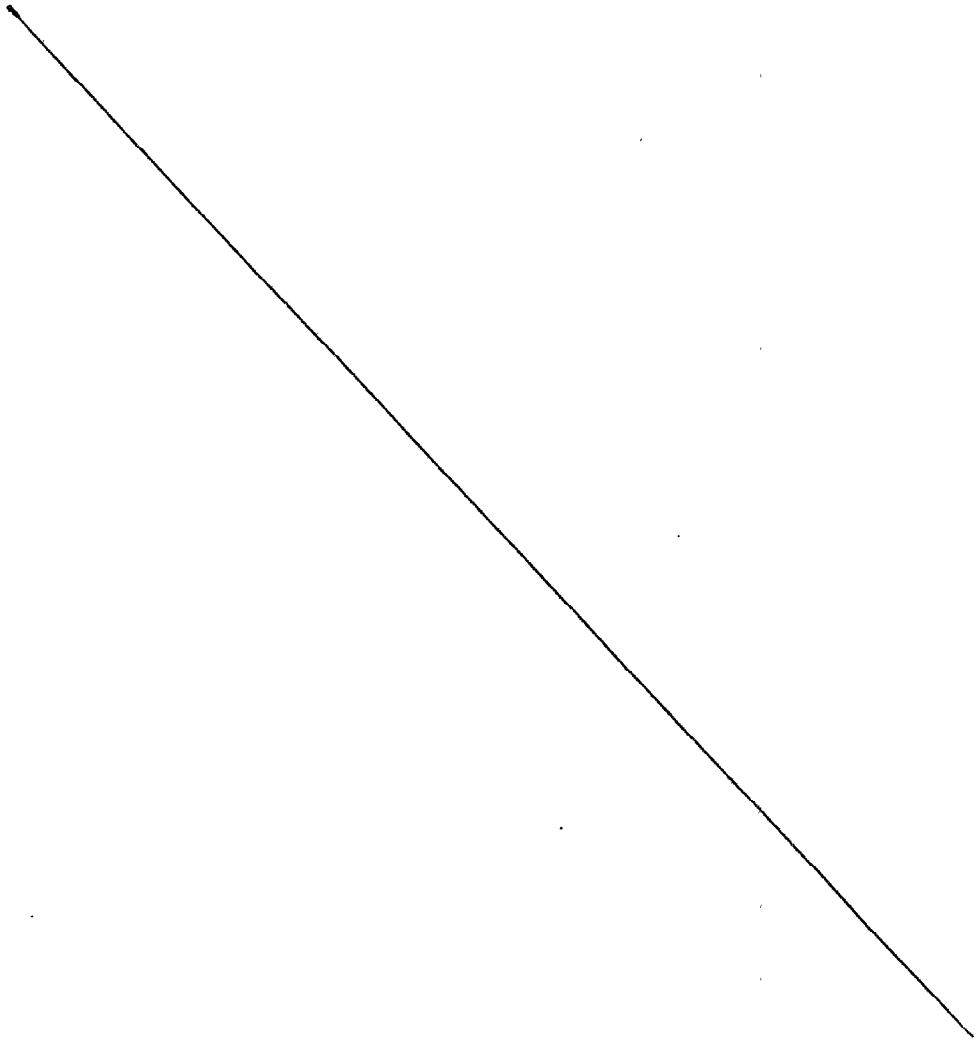
FDA is announcing the availability of a draft guidance for industry entitled "Recommended Approaches to Integration of Genetic Toxicology Study Results." Risk for carcinogenesis is usually determined in rodent assays, in either 2–year studies or shorter-term studies using alternative models (ICH S1B). Regulatory decisions involving both single- and repeat-dose clinical studies are discussed in this guidance. Pharmaceuticals administered through oral, intravenous, topical, and other routes, as appropriate, are subject to this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on recommended approaches to integration of genetic toxicology study results. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper

copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 11/23/04
November 23, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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